DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED AK

June 6, 2000

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 – 38

Scott L. Sabo
Director of Operations
Allograft Resources of Wisconsin, Inc.
3553 University Avenue
Madison, Wisconsin 53705

Dear Mr. Sabo:

During an inspection of Allograft Resources of Wisconsin, Inc., conducted on April 5-7, 10-12 and 14, 2000, our investigators documented violations of Section 361 of the Public Health Service Act and Title 21, Code of Federal Regulations, Part 1270 (21 CFR 1270) as follows:

1. Failure to prepare and follow written procedures for designating and identifying quarantined tissue [21 CFR 1270.31(c)] that was shipped directly to the [redacted]

2. Failure to assure tissue was shipped under quarantine and with records identifying the donor and indicating that the tissue had not been determined to be suitable for transplantation [21 CFR 1270.33(b) and (c)] for at least 15 donations shipped to th[redacted]

3. Failure to maintain an accurate record of tissue distribution [21 CFR 1270.35(c)] in that donor files indicate skin was sent to LifeCell Corporation when it was actually sent to the [redacted]

4. Failure to maintain the records used to determine the suitability of donors [21 CFR 1270.33(f)] in that at least [redacted] donor files are missing records generated by your firm. The missing records include Donor Medical Social

History Questionnaire, Infusion Summary, Procurement Specialist Information Worksheet, Recovery Log Part I, and Physical Examination Log.

5. Failure to maintain accurate records [21 CFR 1270.33(a)] in that several donor files are incomplete, record keeping forms are completed as rough drafts and are therefore not indelible or permanent, there is no file for at least one deferred donor, and reasons for deferral are not always documented. The files also contain discrepancies such as the type of tissue that was recovered and the donor's health history.

6. Failure to have written procedures readily available to personnel who perform the procedures [21 CFR 1270.31(b)] in that a copy of relevant procedures do not accompany the procurement team to the recovery location.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice which may include Order for Retention, Recall and/or Destruction, and/or Injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your written response should be directed to Compliance Officer Judy E. Heisick at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

JEH/ccl